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EXAMINER	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/802,273	RODRIGUEZ, GUSTAVO C.	
	Examiner	Art Unit	
	Leslie A. Royds	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 October 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____is/ are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-24 are presented for examination.

A request for continued examination under 37 C.F.R. 1.114, including the fee set forth in 37 C.F.R. 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 C.F.R. 1.114, and the fee set forth in 37 C.F.R. 1.17(e) has been timely paid, the finality of the previous Office Action has been withdrawn pursuant to 37 C.F.R. 1.114. Applicant's payment and submission filed October 31, 2007 has been received and entered into the present application. Accordingly, prosecution has been reopened.

Claims 1-24 remain pending and under examination. Claim 22 is amended.

Applicant's arguments, filed October 31, 2007, have been fully considered. Rejections not reiterated from previous Office Actions are hereby withdrawn. The following rejections are either reiterated or newly applied. They constitute the complete set of rejections presently being applied to the instant application.

Claim Rejections - 35 USC § 112, First Paragraph, Written Description Requirement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 20-22 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, for the reasons of record set forth at pages 2-4 of the previous Office Action dated August 22, 2007, of which said reasons are herein incorporated by reference.

Applicant traverses the instant rejection, relying upon Table 2, p.6, of the specification, which describes a tri-phasic product with norgestimate having dosages in the range of 0.18-0.25 mg of norgestimate, as well as p.13, l.3-7, which conveys the concept of altering the dosage of the progestin

product to reduce the risk of ovarian cancer. Applicant additionally relies upon the disclosure at p.35, l.19-24 to allegedly support the concept of altering the progestin dosage in an OCP product with norgestimate, using at least 0.5 mg norgestimate and a tri-phasic regimen. Still further, Applicant alleges that the specification clearly conveys to one skilled in the art that one of the phases has at least 0.5 mg norgestimate and non-altered phases have norgestimate dosages in the range of 0.18-0.25 mg such that the specification supports the concept that, for the phases that are not altered in accordance with the feature of increasing the progestin to increase apoptosis, the inventor had possession of an invention wherein the remaining phases use a standard level of 0.18-0.25 mg norgestimate.

Applicant's traversal has been fully and carefully considered, but fails to be persuasive.

Reliance upon the instant specification at pages 6, 13 and 35 has again been fully considered, but fails to provide adequate written support to demonstrate that Applicant was in possession of the concept of a multi-phasic hormonal regimen wherein one norgestimate phase has a daily dosage of at least 0.5 mg and another phase has a daily dosage of 0.18-0.25 mg norgestimate, specifically 0.18 mg or 0.215 mg. Applicant's Table 2 at page 6 describes the composition of selected marketed oral contraceptive regimens, but fails to provide any teaching or suggestion to modify any one of these known prior art contraceptive regimen in accordance with the described advantages of the instant invention, namely, the inclusion of one phase having a daily dosage of norgestimate of at least 0.5 mg and at least 20 to less than 35 mcg ethinyl estradiol (EE) equivalent into a multi-phasic regimen wherein one of the other phases has a daily dosage of norgestimate of 0.18-0.25 mg, specifically 0.18 mg or 0.215 mg.

Applicant provides a diffuse suggestion to combine formulations at page 49 of the instant specification, which states, "Alternatively, another agent could be added to one or more of the tablets of the OCP formulations, including any of the formulations described in the Background, to regulate TGF-beta expression and/or increase apoptotic induction, or by adding another progestin or changing the progestin to one which is more potent for TGF-beta expression upregulation or apoptotic effect or

alteration of expression of surrogate biomarkers of ovarian epithelium cancer protection." This *suggestion*, however, fails to provide any teaching, either explicit or implicit, to specifically combine a phase out of any one of these background (prior art) formulations, let alone the specific ORTHO TRI-CYCLEN regimen, into the composition(s) disclosed as the invention, i.e., a hormonal regimen comprising one phase having a daily dosage of norgestimate of 0.5 mg and at least 20 to less than 35 mcg EE equivalent.

Note that picking and choosing among various embodiments to arrive at a single embodiment that was not so described in the originally filed disclosure or claims as a specifically contemplated embodiment fails to constitute a showing of possession. What may be suggested by the disclosure or what may be an "obvious modification" to what is disclosed (such as, e.g., by combining individual elements of various disclosed embodiments) is insufficient to establish possession under the written description requirement of 35 U.S.C. 112, first paragraph, because it fails to demonstrate that Applicant had contemplated and/or envisaged such an embodiment at the time of the invention. Please see MPEP §2163.

Even if, *arguendo*, the specification did provide a specific suggestion to combine Applicant's inventive regimen with that of the prior art regimen of ORTHO TRI-CYCLEN (which the Examiner does not concede), it is noted that the description of the three individual phases of ORTHO TRI-CYCLEN, each with a specific daily norgestimate dose of 0.18 mg, 0.215 mg or 0.25 mg, clearly fails to provide adequate written support to then claim a phase with a daily norgestimate dose of from 0.18-0.25 mg, since the regimen and/or the specification fails to contain a teaching of any dosage amounts between 0.18-0.215 mg and 0.215-0.25 mg norgestimate. For this reason, such a range would represent a broadening of the subject matter both claimed and disclosed in the specification and claims as originally filed that is not adequately supported, either explicitly or implicitly, by the original disclosure. In addition, the description of the three phases each combined with an estrogen component (i.e., ethinyl estradiol at a

fixed daily dosage of 35 mcg) clearly fails to provide adequate written support to then claim the use of any one of the norgestimate phase(s) with a daily dose of 0.18 mg, 0.215 mg or 0.25 mg norgestimate in the absence of 35 mcg ethinyl estradiol. The use of such a phase in the absence of the ethinyl estradiol component represents a broadening of the subject matter both claimed and disclosed in the specification and claims as originally filed that is not adequately support, either explicitly or implicitly, by the original disclosure.

For these reasons described *supra*, and those previously made of record at pages 2-4 of the previous Office Action dated August 22, 207, rejection of claims 20-22 remains proper and is **maintained**.

Claim Rejections - 35 USC § 112, First Paragraph, Written Description Requirement

(New Grounds of Rejection)

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 16-19 and 23-24 are rejected under 35 U.S.C. 112, first paragraph; as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

MPEP §2163 states, "The courts have described the essential question to be addressed in a description requirement issue in a variety of ways. An objective standard for determining compliance with the written description requirement is, "does the description clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed." *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989). Under *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19

USPQ2d 1111, 1117 (Fed. Cir. 1991), to satisfy the written description requirement, an applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention, and that the invention, in that context, is whatever is now claimed. The test of sufficiency of support in a parent application is whether the disclosure of the application relied upon "reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter." *Ralston Purina Co. v. Far-Mar-Co., Inc.*, 772 F.2d 1570, 1575, 227 USPQ 177, 179 (Fed. Cir. 1985) (quoting *In re Kaslow*, 707 F.2d 1366, 1375, 217 USPQ 1089, 1096 (Fed. Cir. 1983))...Whenever the issue arises, the fundamental factual inquiry is whether the specification conveys with reasonable clarity to those skilled in the art that, as of the filing date sought, applicant was in possession of the invention as now claimed. See, e.g., *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991)."

Instant Claim 16

In particular, the specification and claims as originally filed fail to provide adequate written support for the limitation directed to "with one phase having a daily dosage of norgestimate of at least 0.8 mg and another phase having a daily dosage of norgestimate of 0.2-0.3 mg."

Applicant discloses a hormonal regimen comprising daily sequentially dosages wherein at least one of the daily dosages comprises at least 0.5 mg norgestimate and an estrogen component in the range of 20-35 mcg ethinyl estradiol (EE) equivalent, further wherein the regimen may be multi-phasic at the paragraph bridging pages 35-36 of the instant specification. Applicant additionally discloses at p.48, para.1, a contraceptive regimen comprising a progestin, e.g., 200-300 μg norgestimate, with an estrogen (15-25 μg EE dosage equivalent).

However, such disclosure of two distinct regimens, one a multi-phasic regimen containing at least 0.5 mg norgestimate and an estrogen component in the range of 20-35 mcg EE equivalent, wherein one phase has a daily dosage of norgestimate of at least 0.8 mg, and a completely separate regimen containing

15-25 μg EE equivalent and 200-300 μg (i.e., 0.2-0.3 mg) norgestimate is not adequate written support to now narrow the claims to read upon a regimen containing at least 0.5 mg norgestimate and an estrogen component in the range of 20-35 mcg EE equivalent, wherein one phase has a daily dosage of norgestimate of at least 0.8 mg and another phase has a daily dosage of 0.2-0.3 mg norgestimate when such an embodiment was neither disclosed in the specification nor the claims as originally filed. This is a narrowing of the subject matter both claimed and disclosed in the specification and claims as originally filed that is not adequately supported, either explicitly or implicitly, by the original disclosure. It is clear, therefore, that Applicant was not in possession of the concept of the hormonal regimen now recited in claim 16, but rather was solely in possession of the concept of (1) a regimen containing at least 0.5 mg norgestimate and an estrogen component in the range of 20-35 mcg EE equivalent, wherein one phase has a daily dosage of norgestimate of at least 0.8 mg **or** (2) a regimen containing 15-25 μg EE equivalent and 200-300 μg (i.e., 0.2-0.3 mg) norgestimate.

Instant Claim 17

In particular, the specification and claims as originally filed fail to provide adequate written support for the limitation directed to "wherein said regimen consists of a 21-28 daily dosages for a cycle, and wherein the total norgestimate in said cycle is at least 8 mg."

Applicant discloses a hormonal regimen comprising daily sequentially dosages wherein at least one of the daily dosages comprises at least 0.5 mg norgestimate and an estrogen component in the range of at least 20 to less than 35 mcg ethinyl estradiol (EE) equivalent, further wherein the regimen provides a total dosage of norgestimate in a cycle not to exceed 8 mg and the cycle is preferably 28 days in length at the paragraph bridging pages 35-36 of the instant specification.

However, such disclosure of (1) a total dosage of norgestimate not to exceed 8 mg and (2) a cycle length of 28 days is not adequate written support to now broaden the claims to read upon a regimen containing at least 0.5 mg norgestimate and an estrogen component of at least 20 to less than 35 mcg EE

equivalent, wherein (1) the total dosage of norgestimate is *at least 8 mg* and (2) the cycle length is from 21-28 days when such an embodiment was neither disclosed in the specification nor the claims as originally filed. This is a broadening of the subject matter both claimed and disclosed in the specification and claims as originally filed that is not adequately supported, either explicitly or implicitly, by the original disclosure. It is clear, therefore, that Applicant was not in possession of the concept of the hormonal regimen now recited in claim 17, but rather was solely in possession of the concept of a regimen containing at least 0.5 mg norgestimate and an estrogen component of at least 20 to less than 35 mcg EE equivalent, wherein the total daily dosage of norgestimate *does not exceed* 8 mg and the cycle length is 28 days.

Instant Claim 18

In particular, the specification and claims as originally filed fail to provide adequate written support for the limitation directed to "wherein said total norgestimate in said cycle is at least 12 mg."

Applicant discloses a hormonal regimen comprising daily sequentially dosages wherein at least one of the daily dosages comprises at least 0.5 mg norgestimate and an estrogen component in the range of 20-35 mcg ethinyl estradiol (EE) equivalent, further wherein the regimen provides a total dosage of norgestimate in a cycle not to exceed 8 mg or not to exceed 10 mg or not to exceed 15 mg at the paragraph bridging pages 35-36 of the instant specification. Applicant additionally discloses a hormonal regimen comprising daily sequentially dosages wherein at least one of the daily dosages comprises at least 0.5 mg norgestimate and an estrogen component in the range of 25-35 mcg ethinyl estradiol (EE) equivalent, further wherein the regimen provide a total dosage of norgestimate in a cycle exceeding 12 mg at para.1, p.54 of the instant specification.

However, such disclosure of two distinct regimens, one a regimen containing at least 0.5 mg norgestimate and an estrogen component in the range of 20-35 mcg EE equivalent, wherein the total dose of norgestimate does not exceed 8 mg or 10 mg or 15 mg, and a completely separate regimen containing

at least 0.5 norgestimate and 25-35 μg EE equivalent, wherein the total dose of norgestimate exceeds 12 mg, is not adequate written support to now broaden the claims to read upon a regimen containing at least 0.5 mg norgestimate and an estrogen component in the range of 20-35 mcg EE equivalent, wherein the total dosage of norgestimate is at least 12 mg, when such an embodiment was neither disclosed in the specification nor the claims as originally filed. This is a broadening of the subject matter both claimed and disclosed in the specification and claims as originally filed that is not adequately supported, either explicitly or implicitly, by the original disclosure. It is clear, therefore, that Applicant was not in possession of the concept of the hormonal regimen now recited in claim 18, but rather was solely in possession of the concept of (1) a regimen containing at least 0.5 mg norgestimate and an estrogen component in the range of 20-35 mcg EE equivalent, wherein the total dose of norgestimate does not exceed 8 mg or does not exceed 10 mg or does not exceed 15 mg **or** (2) a regimen containing at least 0.5 norgestimate and 25-35 μg EE equivalent, wherein the total dose of norgestimate exceeds 12 mg.

Instant Claim 19

In particular, the specification and claims as originally filed fail to provide adequate written support for the limitation directed to "wherein said total norgestimate in said cycle is at least 20 mg."

Applicant discloses a hormonal regimen comprising daily sequentially dosages wherein at least one of the daily dosages comprises at least 1.2 mg norgestimate and an estrogen component in the range of 20-35 mcg ethinyl estradiol (EE) equivalent, wherein the total dose of norgestimate does not exceed 8 mg or 10 mg or 15 mg, at the paragraph bridging pages 35-36 of the instant specification. Applicant additionally discloses a hormonal regimen comprising daily dosages of an estrogen component in the range of 25-35 mcg ethinyl estradiol (EE) equivalent and a total dosage of norgestimate in a cycle to exceed 20 mg at para.2, p.36 of the instant specification.

However, such disclosure of two distinct regimens, one a regimen containing at least 1.2 mg norgestimate and an estrogen component in the range of 20-35 mcg ethinyl estradiol (EE) equivalent,

wherein the total dose of norgestimate does not exceed 8 mg or 10 mg or 15 mg, and a completely separate regimen containing daily dosages of an estrogen component in the range of 25-35 mcg ethinyl estradiol (EE) equivalent and a total dosage of norgestimate in a cycle to exceed 20 mg, is not adequate written support to now broaden the claims to read upon a regimen containing at least 1.2 mg norgestimate and an estrogen component in the range of 20-35 mcg EE equivalent, wherein the total dosage of norgestimate is at least 20 mg, when such an embodiment was neither disclosed in the specification nor the claims as originally filed. This is a broadening of the subject matter both claimed and disclosed in the specification and claims as originally filed that is not adequately supported, either explicitly or implicitly, by the original disclosure. It is clear, therefore, that Applicant was not in possession of the concept of the hormonal regimen now recited in claim 19, but rather was solely in possession of the concept of (1) a regimen containing at least 1.2 mg norgestimate and an estrogen component in the range of 20-35 mcg ethinyl estradiol (EE) equivalent, wherein the total dose of norgestimate does not exceed 8 mg or 10 mg or 15 mg **or** (2) a regimen containing daily dosages of an estrogen component in the range of 25-35 mcg ethinyl estradiol (EE) equivalent and a total dosage of norgestimate in a cycle to exceed 20 mg.

Instant Claim 23

In particular, the specification and claims as originally filed fail to provide adequate written support for the limitation directed to "with one phase having a daily dosage of norgestimate of at least 0.5 mg and has another phase with a daily dosage of norgestimate of 0.2-0.3 mg."

Applicant discloses a hormonal regimen comprising daily sequentially dosages wherein at least one of the daily dosages comprises at least 0.5 mg norgestimate and an estrogen component in the range of 20-35 mcg ethinyl estradiol (EE) equivalent, further wherein the regimen may be multi-phasic at the paragraph bridging pages 35-36 of the instant specification. Applicant additionally discloses at p.48, para.1, a contraceptive regimen comprising a progestin, e.g., 200-300 μg norgestimate, with an estrogen (15-25 μg EE dosage equivalent).

However, such disclosure of two distinct regimens, one a multi-phasic regimen containing at least 0.5 mg norgestimate and an estrogen component in the range of 20-35 mcg EE equivalent, wherein one phase has a daily dosage of norgestimate of at least 0.5 mg, and a completely separate regimen containing 15-25 μg EE equivalent and 200-300 μg (i.e., 0.2-0.3 mg) norgestimate is not adequate written support to now narrow the claims to read upon a regimen containing at least 0.5 mg norgestimate and an estrogen component in the range of 20-35 mcg EE equivalent, wherein one phase has a daily dosage of norgestimate of at least 0.5 mg and another phase has a daily dosage of 0.2-0.3 mg norgestimate when such an embodiment was neither disclosed in the specification nor the claims as originally filed. This is a narrowing of the subject matter both claimed and disclosed in the specification and claims as originally filed that is not adequately supported, either explicitly or implicitly, by the original disclosure. It is clear, therefore, that Applicant was not in possession of the concept of the hormonal regimen now recited in claim 23, but rather was solely in possession of the concept of (1) a regimen containing at least 0.5 mg norgestimate and an estrogen component in the range of 20-35 mcg EE equivalent, wherein one phase has a daily dosage of norgestimate of at least 0.5 mg **or** (2) a regimen containing 15-25 μg EE equivalent and 200-300 μg (i.e., 0.2-0.3 mg) norgestimate.

Instant Claim 24

In particular, the specification and claims as originally filed fail to provide adequate written support for the limitation directed to "wherein said regimen consists of a 20-35 daily dosages for a cycle, and wherein the total norgestimate in said cycle is at least 8 mg."

Applicant discloses a hormonal regimen comprising daily sequentially dosages wherein at least one of the daily dosages comprises at least 0.5 mg norgestimate and an estrogen component in the range of at least 20 to less than 35 mcg ethinyl estradiol (EE) equivalent, further wherein the regimen provide a total dosage of norgestimate in a cycle not to exceed 8 mg and the cycle is preferably 28 days in length at the paragraph bridging pages 35-36 of the instant specification. Applicant additionally discloses a

hormonal regimen comprising daily sequentially dosages wherein at least one of the daily dosages comprises at least 0.5 mg norgestimate and an estrogen component in the range of 25-35 mcg ethinyl estradiol (EE) equivalent, further wherein the regimen provide a total dosage of norgestimate in a cycle exceeding 8 mg and the cycle of 20-35 days in length at para.1, p.54 of the instant specification.

However, such disclosure of two distinct regimens, one a regimen containing at least 0.5 mg norgestimate and an estrogen component in the range of 20-35 mcg EE equivalent, wherein the total dose of norgestimate does not exceed 8 mg and the cycle is 28 days in length, and a completely separate regimen containing at least 0.5 norgestimate and 25-35 μg EE equivalent, wherein the total dose of norgestimate exceeds 8 mg and the cycle is 20-35 days, is not adequate written support to now broaden the claims to read upon a regimen containing at least 0.5 mg norgestimate and an estrogen component in the range of at least 20 to less than 35 mcg EE equivalent, wherein the total dosage of norgestimate is at least 8 mg and the cycle is 20-35 days in length, when such an embodiment was neither disclosed in the specification nor the claims as originally filed. This is a broadening of the subject matter both claimed and disclosed in the specification and claims as originally filed that is not adequately supported, either explicitly or implicitly, by the original disclosure. It is clear, therefore, that Applicant was not in possession of the concept of the hormonal regimen now recited in claim 24, but rather was solely in possession of the concept of (1) a regimen containing at least 0.5 mg norgestimate and an estrogen component in the range of 20-35 mcg EE equivalent, wherein the total dose of norgestimate does not exceed 8 mg and the cycle is 28 days in length **or** (2) a regimen containing at least 0.5 norgestimate and 25-35 μg EE equivalent, wherein the total dose of norgestimate exceeds 8 mg and the cycle is 20-35 days in length.

As stated in MPEP §2163, "The subject matter of the claim need not be described literally (i.e., using the same terms of *in haec verba*) in order for the disclosure to satisfy the description requirement." However, considering the teachings provided in the specification as originally filed, Applicant has failed

to provide the necessary teachings, by describing the claimed invention, in such a way as to reasonably convey to one skilled in the relevant art that Applicant had possession of the limitations of instant claims 16-19 and 23-24 as discussed *supra*.

Accordingly, the claims are considered to lack sufficient written description and are properly rejected under 35 U.S.C. 112, first paragraph.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-24 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Pasquale (U.S. Patent No. 4,544,554; 1985) in view of Elliesen et al. (WO 97/11680; 1997), each already of record, for the reasons of record set forth at pages 5-11 of the previous Office Action dated August 22, 2007, of which said reasons are herein incorporated by reference.

Applicant traverses the instant rejection, stating that the Examiner has failed to show a reason that would have prompted the artisan to arrive at the claimed invention from anything taught in the prior art references. Applicant alleges that "common sense would have suggest *[sic]* the opposite" and further alleges that "there has been a movement to decrease the amount of progestin and estrogen" (p.6, Remarks). Still further, Applicant states that there is nothing in the reference to Pasquale that would suggest a combination of the regimens disclosed in Examples 2 and 4 and additionally asserts that Pasquale fails to teach anything regarding the weight of the user or anything else that would prompt the artisan to arrive at the claimed invention.

Applicant's traversal has been fully and carefully considered, but fails to be persuasive.

The basis of Applicant's traversal is unclear. The previous rejection clearly addressed the scope and content of the prior art to Pasquale, ascertained the differences between Pasquale and the claimed invention and resolved the differences between the prior art and the present invention with cogent reasoning provided at pages 5-10. In the absence of any specific articulation by Applicant as to what particular elements, in fact, are believed to be missing from this reasoning such that it failed to demonstrate why the artisan would have arrived at the claimed invention, Applicant's remarks to this effect are not found persuasive in view of the extensive discussion, reasoning and motivation provided at pages 5-10 of the previous Office Action dated August 22, 2007.

Moreover, Applicant alleges that "there has been a movement to decrease the amount of progestin and estrogen" and further asserts that, if a skilled artisan were to decrease the amount of progestin in Example 2, then the artisan would do it for all three phases, but advances no specific reasons or evidence, aside from Counsel's own speculation, in support of this position. This assertion by Counsel is an unsupported allegation and fails to take the place of evidence in the record. Statements of this nature are clearly unpersuasive in accordance with the guidance provided at MPEP §2145, which states, "The arguments of counsel cannot take the place of evidence in the record. *In re Schulze*, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965); *In re Geisler*, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997)".

In addition, the position that the skilled artisan would only be motivated to decrease the amount of progestin in each of the three phases is not persuasive in view of the teachings of Elliesen et al., who provides an *express* and *explicit* teaching that frequent modifications to the progesterone dosage level are necessary to deal with hormonal fluctuations due to the physiological differences between women, such as, e.g., variations in body weight and fat mass, time of reproductive cycle, menses, menopause, age, weight, lean muscle/fat mass ratio, etc. For this reason, the skilled artisan would have been clearly aware of the need to provide modifications to the amount of progesterone used. In view of this fact, Applicant's allegation that the artisan would have made a blanket decrease in progesterone across all phases is

inconsistent with the teachings of the prior art, since the artisan would rather have been motivated to tailor the amount administered (either by increasing or decreasing the dose, as appropriate) to the patient's needs at the time of administration.

Further, Applicant's allegation that there is nothing in the reference to Pasquale that would suggest a combination of the regimens disclosed in Examples 2 and 4 is not persuasive in view of the reasoning provided in the paragraph bridging pages 9-10. Specifically, it was noted that Pasquale expressly teaches an exemplary regimen (Example 4) wherein norgestimate is administered concomitantly with 0.035 mg 17alpha-ethinylestradiol in three phases of 0.18 mg norgestimate, 0.215 mg norgestimate and 0.25 mg norgestimate, which has the same contraceptive efficacy as compared to the regimen of Example 2, which contains norgestimate in an amount of at least 0.5 mg. In view of these teachings, the Office Action stated that it would have been *prima facie* obvious to the skilled artisan to employ a phase according to Example 4 in the hormonal regimen disclosed by Pasquale because prolonged treatment with excessively high levels of progestogen can lead to hormonal side effects such as, but not limited to, those taught by Elliesen et al. at the top of page 2, including breast tenderness, nausea, edema, menstrual disorders, etc. Therefore, the contraceptive efficacy of a multi-phasic regimen would have been maintained with this combination of phases but with the advantage of avoiding the adverse side effects typically seen with protracted administration of high levels of progestogen(s), absent factual evidence to the contrary.

In view of this clearly set forth motivation to combine the cited references, the basis of Applicant's argument that a *prima facie* case of obviousness has not been set forth due to a lack of direction in Pasquale is unpersuasive. In the event that Applicant is making this assertion based upon the fact that the cited references do not *explicitly provide an exact statement of motivation* to make the exact combination as presently claimed, Applicant is initially reminded that an express motivation to combine is not required to be explicitly stated in the prior art in order to construct a finding of obviousness. Please

reference MPEP §2145(X), which states, "However, there is no requirement that an express, written motivation to combine must appear in the prior art references before a finding of obviousness."

Note, also, that the references applied under 35 U.S.C. 103(a) are not required to contain specific statements that would spell out the claimed invention in order to construct a finding of obviousness, since questions of obviousness involve not only what references expressly teach, but also what they would collectively suggest to one skilled in the art. Please reference *In re Burckel,* 201 USPQ 67 (CCPA). This was reiterated in *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385 (U.S. 2007), which again forecloses the argument that a ***specific*** teaching, suggestion or motivation is required to be located in the cited art in order to support a finding of obviousness. See, e.g., *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385 (U.S. 2007) at 1396.

Applicant is further reminded that analysis under 35 U.S.C. 103(a) need not seek out *precise* teachings directed to the specific subject matter of the challenged claim since the courts can take account of inferences, creative steps and background knowledge that a person of ordinary skill in the art would either employ or have well within their possession. *KSR International Co. v. Teleflex, Inc.* (82 USPQ2d 1385 (2007)) held that issues of obviousness must take into account design incentives, market forces and/or the background knowledge possessed by a person having ordinary skill in the art, such that if a person of ordinary skill in the art can implement a reasonably predictable variation, such as, e.g., in the present case, combining known hormonal regimens together to achieve a lower incidence of adverse side effects by using lower progestogen levels, particularly when such an effect was a known disadvantage to hormonal regimens employing consistently high levels of progestogen, but still maintain contraceptive efficacy, the obviousness standard under 35 U.S.C. 103(a) generally bars its patentability, absent, e.g., a showing that the instantly claimed combination yields unexpected results or other secondary considerations (see MPEP § 2141).

Lastly, in response to Applicant's assertion that Pasquale *per se* does not teach anything

regarding the weight of the user, etc. to modify the dosage amounts, this teaching and suggestion regarding modifying the dosages of progesterone based upon a variety of physiological and hormonal factors, including, but not limited to, weight, age, etc., was found in Elliesen et al. Absent factual evidence to the contrary, one of ordinary skill in the art at the time of the invention would have been aware of the general knowledge in the art regarding the need to adjust the specific dosage levels of progestogen to account for hormonal and physiological fluctuations in individual women (as evidenced by Elliesen et al.) and would have applied this knowledge to known prior art regimens, such as that disclosed by Pasquale.

For these reasons described *supra*, and those previously made of record at pages 5-10 of the previous Office Action dated August 22, 207, rejection of claims 1-24 remains proper and is **maintained**.

Double Patenting (New Grounds of Rejection)

Obviousness-Type Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-2, 5-6, 10 and 12-14 are provisionally rejected on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2, 4, 6-7, 12-13 and 16 of U.S. Patent Application No. 11/931,751 in view of Pasquale (U.S. Patent No. 4,544,554).

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claims

because the examined claims are either anticipated by, or would have been obvious over, the reference claims.

Although the conflicting claims are not identical, the claims of the instant patent application and those of the copending applications are not considered patentably distinct from each other because the pending claims are obvious over the copending claims.

The copending claims clearly provide for a pharmaceutical product comprising a progestin and an estrogen, wherein the estrogen is 17alpha-ethinylestradiol in an amount of 20-35 mcg, and the progestin is norgestimate in an amount of 0.18-0.25 mg to provide contraceptive efficacy.

The patented claims differ from the instant claims insofar as the instant claims require a daily dosage of at least 0.5 mg norgestimate (such as, e.g., 0.5-0.8 mg norgestimate as recited in instant claim 2 or at least 1.0 mg of norgestimate as recited in instant claim 5 or 1.0-2.0 mg norgestimate as recited in instant claim 6).

Pasquale teaches the contraceptive efficacy of contraceptive regimens comprising an estrogen, such as 17alpha-ethinylestradiol in an amount of 0.020-0.050 mg, preferably 0.035 mg (col.2, l.47-54), and a progestin, preferably such as norgestimate (also referred to as D-17beta-acetoxy-13beta-ethyl-17alpha-ethinyl-gon-4-en-3-one-oxime) (col.3, l.3-12), wherein exemplary contraceptive regimens comprise 0.5 mg or 0.75 mg or 1.0 mg of norgestimate (Example 2, col.4). In view of such a teaching, one of ordinary skill in the art would have found it *prima facie* obvious to employ norgestimate in a dosage of 0.5 mg, 0.75 mg or 1.0 mg as the norgestimate components of the composition of the copending claims because, as evidenced by Pasquale, such amounts of norgestimate were known to demonstrate contraceptive efficacy and the composition of the copending claims is intended to provide contraceptive activity (see, e.g., claim 7).

Accordingly, provisional rejection of claims 1-2, 5-6, 10 and 12-14 is proper over claims 1-2, 4, 6-7, 12-13 and 16 of U.S. Patent Application No. 11/931,751 as claiming obvious and unpatentable

variants thereof.

Conclusion

Rejection of claims 1-24 remains proper and is **maintained**.

No claims of the present application are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie A. Royds whose telephone number is (571)-272-6096. The examiner can normally be reached on Monday-Friday (9:00 AM-5:30 PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571)-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Leslie A. Royds
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Art Unit 1614

January 29, 2008

Ardin H. Marschel 1/29/08
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SUPERVISORY PATENT EXAMINER